IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Toyohiko TAKUSHIGE and Etsuro HOSHINO
Serial. No.	:	10/583,500
Filing Date	:	06/19/2006
For	:	Bacterial Intraoral Disease Treatment Composition
Examiner	:	Irina KOSINSKI
Art Unit	:	4131

Honorable Commissioner of Patents and Trademarks
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION UNDER 37 CFR §1.132

I, Toyohiko TAKUSHIGE, a citizen of Japan, do hereby declare the following:

1. I am one of the joint inventors in the above-identified pending United States patent application, and am familiar with the specification, claims, and file history thereof.

2. I graduated from the School of Dentistry, Tohoko University in March, 1972. I obtained my license to practice as a dentist in June, 1972.

I obtained the degree of Doctor of Medical Dentistry from Niigata University in October, 2004.

3. I became a research assistant in the School of Dentistry, Tohoko University in April, 1972, and have been a Professor in the Graduate School of Dentistry, Tohoku University, since April, 2005.

I opened a dental clinic in Sendai City in November, 1980, where I currently practice.

4. I have reviewed the Office Action dated August 7, 2009 issued for the above-referenced patent application, in which Claim 7 is rejected under 35 U.S.C. 102(b) as anticipated by Vermeer (US Patent# 5624906), and Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vermeer.

5. The experiments described below were performed by me, or under my direction. Experiment 1 in the attached documents refers to Test Example 1 of the specification. Tables 1 and 2 of Experiment 1 show that a base including Solbase "a mixture of polyethylene glycol 400 (PEG 400) and polyethylene glycol 4000 (PEG 4000)" of sample #3 and propylene glycol (PG), and a base including PEG 4000 and PG of sample # 4

possess excellent penetrability. From this result, it is understood that a base including PEG 400, PEG 4000, and PG possesses good penetrability. On the other hand, PG of sample #2, PEG 600 of sample #5, and glycerin of sample #6 possess poor penetrability.

6. Experiment 2 in the attached documents includes a photograph showing a state of tooth penetration of a base including PEG 400, PEG 4000 and PG as in Sample #3 of Experiment 1, colored by red food coloring (left side of Fig. 2), and a base including PEG 400, PEG 600, PEG 4000 and PG, in accordance with the invention of present Claim 7, colored by red food coloring (right side of Fig. 2). In Fig. 2 of Experiment 2, the base penetrates the tooth deeply on the right side, in comparison to the left side. Therefore, the base including PEG 400, PEG 600, PEG 4000 and PG of the present invention possesses superior penetrability compared to the penetrability of the mixture in the absence of PEG 600. These results were quite unexpected in view of the poor penetrability exhibited by PEG 600 alone.

7. I hereby declare that all statements made herein are to my own knowledge true and that all statements made on information and assumptions are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

November 6, 2009
Date

宅重豊彦
Toyohiko TAKUSHIGE

Annex

Experiment 1

Fig. 1 depicts a cross-sectional view of a sample 50 according to the present experiment.

First, the mandibular first premolar affected with apical periodontitis was drilled with a #70 reamer to enlarge the root canal and further the root canal 51 was filled using a gutta-percha point and a sealer, and by pressing them sideways. Subsequently a nearly cylindrical hole about 2 mm deep from the cervical line and about 1.5 mm in diameter was formed (hereinafter this hole is referred to as the drug application seat 52 of the above-described administering site). At the bottom of this drug application seat 52, two small pieces 53 (about 1.0 mm in diameter) of each base shown in Table 1 added with food red were loaded. Furthermore, cotton ball (not shown) was placed so as to cover these small pieces 53, and "Caviton (registered trade mark)" (G C Co., Ltd.) was layered over this cotton ball to form the covering layer 54, thereby preparing the sample 50.

After the root portion of each sample 50 was embedded in an ordinary gypsum block 55, it was stored under 100% humidity.

Table 1

Sample No.	Composition
1	Water
2	Propylene glycol
3	"Solbase (brand name)":propylene glycol = 1:1 (mass ratio)
4	Polyethylene glycol 4000:propylene glycol = 3:1 (mass ratio)
5	Polyethylene glycol 600
6	Glycerin

Migration distances of food red from the drug application seat for storing times of 24 hours and 48 hours were measured to assess the penetrability of the base contained in each sample. These results are shown in Table

2. In this case, the migration distance was determined as the longest distance in the direction of depth (in the direction of the arrow D in Fig. 7) of the area reached by coloring due to food red when the sample 50 was observed from outside.

Table 2

Sample No.	Migration distance of food red from drug application seat (depth direction); in mm	
	24 hours	48 hours
1	2.0	4.0
2	2.0	3.5
3	5.0	16.0
4	9.5	18.5
5	3.5	4.0
6	5.0	7.0

As shown in Table 2, it was proved that penetrability of the base is best in sample #4, that is, the base containing polyethylene glycol and propylene glycol. Herein sample #4 contained polyethylene glycol 4000 and propylene glycol in a 3:1 ratio by mass, in other words, in a 1:1 volume ratio.

Experiment 2

Sample #7 is a base including PEG 400, PEG 4000 and PG, and sample #8 is a base including PEG 400, PEG 600, PEG 4000 and PG. Using these bases, penetrability was evaluated in the same way as in Experiment 1.

The left side of Fig. 2 is a photograph showing a state of tooth penetration of red food coloring in the case of sample 7, and the right side is a photograph showing a state of tooth penetration of red food coloring in the case of sample 8.

From these photographs, it is understood that the food coloring penetrates the tooth deeply in the case of sample 8 using the base of the present invention, in comparison to sample 7.

Fig. 1

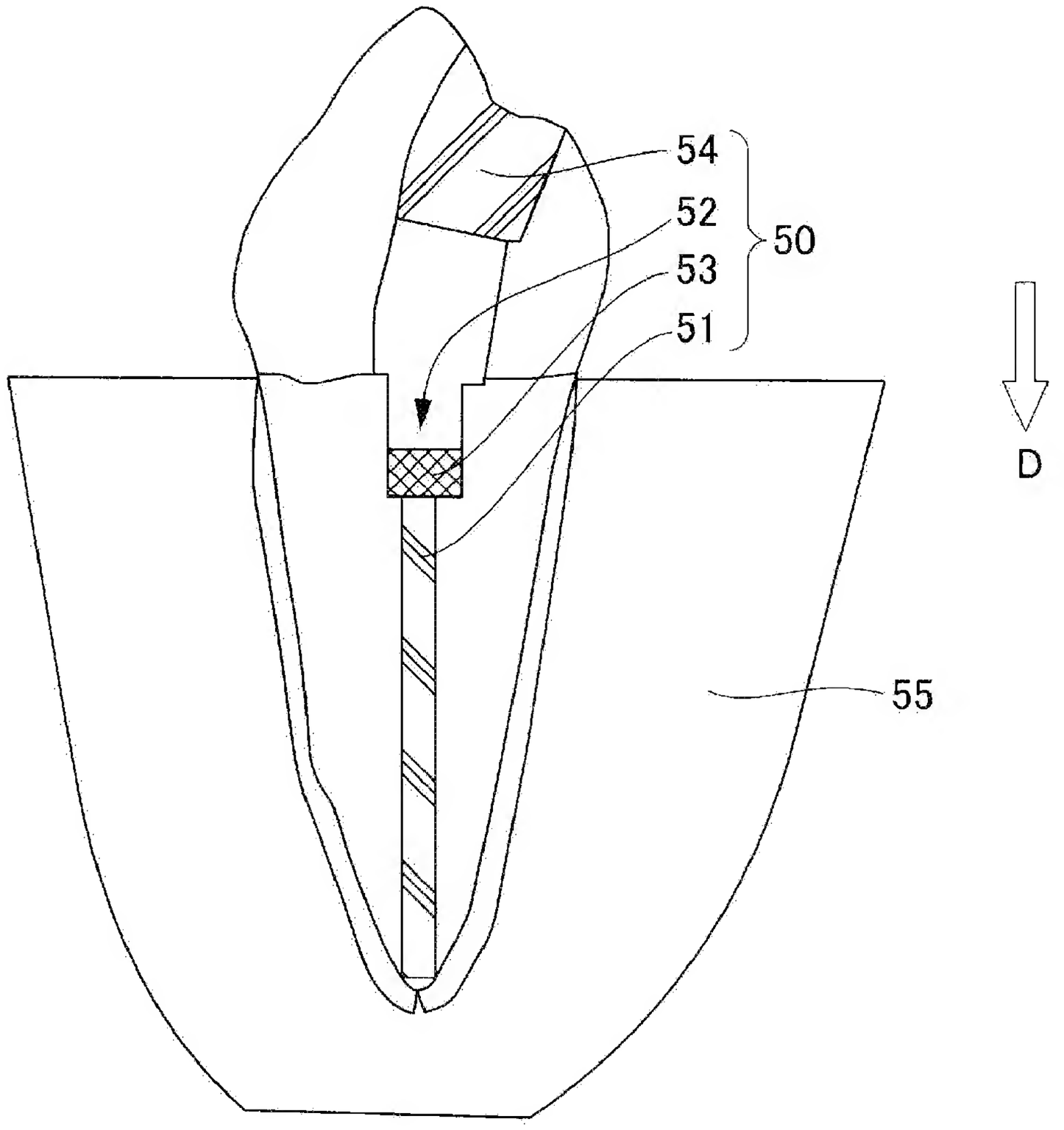

Fig. 2